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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Heinz Rupp

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CLARK & BRODY

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Alexandria, VA 22314

EXAMINER

TANNER, JOCELYN C

ART UNIT

PAPER NUMBER

3731

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/568,430	Applicant(s) RUPP ET AL.	
	Examiner JOCELIN C. TANNER	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1, 4-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to the Amendment filed 31 August 2009. Claims 1 and 4-15 are currently pending. The Examiner acknowledges the amendments to claim 1 and the cancellation of claims 2 and 3.

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, a closed suction head must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1 and 4-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Regarding claim 1, the recitation "measuring the pressure when the suction head is closed" is vague and indefinite. It is unclear if the term "closed" is referring to the end of the suction head being sealed, the recess being closed or sealed, the recess being blocked/clogged since the drawings of the instant application do not appear to show this claimed limitation. For the purposes of art rejections, the closed suction head will be interpreted to be a suction head having a sealed distal end. It is also unclear if the detector required in (b) and the pressure sensor required in (c) are one in the same wherein the pressure sensor is a detector that detects and measure a pressure or a change in pressure. For the purposes of art rejections, the detector is a pressure sensor that is capable of measuring a pressure or a change in pressure.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. **Claims 1, 4-10 and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fleener et al. (US PGPub No. 2004/0127767A1) in view of Lobdell (US Patent No. 6,743,245) and in view of Wendlandt (US Patent No. 6,728,565).**

3. Regarding claim 1, Fleener et al. discloses an apparatus for puncturing or manipulating tissue including a guide device (100) in the form of a rigid or flexible tube, at least one penetrating element (12) which is guided on the guide device and is capable of being advanced, retracted and rotated within the guide device by a control unit (106), a suction that is created by a vacuum source, a closed suction head (40) wherein the distal end is sealed (42), the suction head having at least one recess (60) that is a lateral aperture, wherein tissue attachment at an appropriate site of the apparatus is observed or "detected" by an attachment detection system wherein an imaging device displays the views of tissue disposed adjacent to the outside surface of the housing on a display unit (200) [0013, 0014, 0016, 0018, 0020, 0041, 0044, 0045, 0048]. However, Fleener et al. fails to provide a partial vacuum source that is a continuously operating source of partial vacuum in order to compensate any leakages during attachment, the attachment detection system including at least one detector and pressure sensor that measure pressure or a change in pressure, the attachment detection being attained by prior calibration or adjustment by measuring the pressure.

Lobdell teaches a surgical instrument (50) having a port (16) that receives tissue that is severed by a cutting member (14), the tissue being aspirated by a vacuum source (60) and wherein sensors, a flow meter (82) and a pressure transducer (84) are

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located within the surgical system and are coupled to the aspiration line (64) to detect the change in flow or vacuum caused by tissue occlusion of the port, the sensors being electronically connected to microcontroller (54a), the pressure transducer having the capability of measuring the pressure when the suction head is closed to detect attachment (column 5, lines 30-60).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the device of Fleener et al. with an attachment detection system including a pressure sensors and a detector, as taught by Lobdell, to detect a change in flow or vacuum when occlusion occurs within the recess (column 5, lines 30-60).

Wendlandt teaches an apparatus including a various sensors and orifices (100) located on the distal tip of a catheter (10) wherein a vacuum source draws tissue through the orifices, the suction being controlled by a suction adjustment knob (170) that is capable of maintaining the strength of the vacuum force to maintain sufficient contact between the tissue and the sensors (column 3, lines 25-60).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the device of the combination of Fleener et al. and Lobdell with a continuously operating source of partial vacuum, as taught by Wendlandt, to maintain contact between the tissue and sensors to perform the required analysis and diagnosis (column 3, lines 25-63).

4. Regarding claim 4, Wendlandt teaches an optic sensor that is capable of detecting tissue attachment (column 2, lines 55-65).

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5. Regarding claim 5, Fleener et al. discloses an endoscope (100) that may be provided with a light source and capable of being used as an optical detector [0045].

6. Regarding claim 6, Wendlandt teaches an electrical detector that is capable of detecting attachment of a tissue (column 2, lines 55-65).

7. Regarding claim 7, Wendlandt teaches an ultrasonic sensor used as an acoustic detector and capable of identifying tissue (column 2, lines 55-65).

8. Regarding claim 8, Fleener et al. discloses a display unit (200) that emits optical signals as the display means [0045].

9. Regarding claim 9, Wendlandt teaches optical signals that are adjustable in intensity or frequency in proportion to the degree of attachment such that the intensity or clarity of the display of the lumen by the optical sensors is dependent on the degree of tissue attachment.

10. Regarding claim 10, Fleener et al. discloses a recess (60) having a lateral aperture wherein tissue has sufficient space to be aspirated [0041, 0043, 0049].

11. Regarding claim 12, the combination of Fleener et al., Lobdell and Wendlandt discloses the claimed invention except for a recess having the dimensions of 8.5mm long, 4mm wide and 3mm deep. It would have been an obvious matter of design choice to have a recess having the dimensions of 8.5mm long, 4mm wide and 3mm deep, since applicant has not disclosed that having a recess with the dimensions of 8.5mm long, 4mm wide and 3mm deep solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with a recess

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having any length, width and depth as long as it does not compromise the structural integrity of the device and allows a medical instrument to access and manipulate tissue.

Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided a recess having the dimensions of 8.5mm long, 4mm wide and 3mm deep, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges of dimensions involves only routine skill in the art. In re Aller, 105 USPQ 233.

12. Regarding claim 13, Fleener et al. discloses a needle (12) as a penetrating element [0041].

13. Regarding claim 14, Fleener et al. discloses a puncture or manipulation that is conducted outside the recess (60) [0046, Fig. 3a].

14. Regarding claim 15, the combination of Fleener et al., Lobdell and Wendlandt discloses a guide device having multiple lumens (108) to guide an element (12) to puncture and manipulate tissue and a suction head (40) that can be repeatedly detached from the guide device ([0040, 0045], Fleener et al.), and a control unit that is separate from the device and that drives element (column 3, lines 25-32, column 6, lines 15-17, Garibaldi et al.).

15. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fleener et al. (US PGPub No. 2004/0127767A1) in view of Lobdell (US Patent No. 6,743,245) and in view of Wendlandt (US Patent No. 6,728,565), as applied to claim 1 above, and further in view of Hamilton (US Patent No. 6,383,198).

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16. Regarding claim 11, the combination of Fleener et al., Lobdell and Wendlandt discloses all of the limitations previously discussed except for a tapered vacuum duct within the guide device.

Hamilton teaches a vacuum duct (32) within a guide device (10) that tapers in a funnel shape toward the vacuum aperture whereby the more pronounced vacuum is located at the vacuum aperture site (column 4, lines 65-67, column 6, lines 5-14, Fig. 3).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the device of the combination of Fleener et al. Lobdell and Wendlandt with a tapered vacuum duct, as taught by Hamilton, to provide a secured and controlled area for a vacuum.

Response to Arguments

17. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOCELIN C. TANNER whose telephone number is (571)270-5202. The examiner can normally be reached on Monday through Thursday between 9am and 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jocelin C. Tanner
3/24/2010
Examiner, Art Unit 3731

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/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3734